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|  | **C3PO: Clinical Trial of COVID-19 Convalescent Plasma in Outpatients** BB.Protocol | **Dept:** | 324311 |
| **Dept Name:** | Blood Bank |
| **Effective Date:** | Title 21 |
| **Revised Date:** | Title 21 |
| **Name & Title**: CLIA Laboratory Medical Director | **Contact:** | Julie H. Simmons/ Christina S Warren |
| **Signature: Refer to Title 21** | **Date:** | **Title 21** |

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1. **General Protocol Statement:**
2. **Purpose:** Convalescent plasma is plasma collected from individuals who have recovered from a particular virus or bacteria. This is given to patients to boost their immunity with the antibodies present from the donor. COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product.  This plasma would contain antibodies to Severe Acute Respiratory Syndrome CoronaVirus 2 or SARS-CoV-2 (the virus that causes COVID-19).

This is a study to administer COVID-19 Convalescent Plasma in Outpatients. This is a study of patients that present to the Emergency Department that will be discharged home following administration of plasma or placebo.

1. **Responsible Department/Scope:**

 i. Procedure owner/Implementer: Julie H. Simmons/ Christina S Warren

 ii. Procedure prepared by: Julie Simmons

 iii. Who performs procedure: Department staff/management

1. **Definitions:**

**ED:** Emergency Department

**BBMD:** Blood Bank Medical Director

**WFBMC:** Wake Forest Baptist Medical Center

**IRB:** Institutional Review Board- an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

**Project Manager:** Stephanie Elliot, sbradsha@wakehealth.edu

**Study Physician:** Simon Mahler

1. **Sections**:
2. Receiving convalescent plasma
3. Ordering convalescent plasma
4. Processing the plasma
5. **Protocol:**
6. **Receiving Convalescent Plasma**

1. Convalescent Plasma for this study will be shipped via UPS.
2. The study plasma will have a packing slip that states: “CCP for C3PO” Study.
3. The supplier will include a Prepaid UPS label to return the shipping container.
	1. The dry ice should be removed before mailing.
4. Enter the plasma into inventory in SCC per SOP.
5. Make a copy of the packing slip.
	1. The original should be given to management.
	2. The copy should be placed on Freezer 11.
6. The C3PO convalescent plasma will be stored in Freezer 11, Drawer 7 to keep it separate from the inpatient convalescent plasma.
7. The study will provide an initial shipment of C3PO convalescent plasma:
	1. Group O (x3)
	2. Group A low titer(x3)
8. Group O patients will receive Group O convalescent plasma (or Group A if needed).
9. Group A, B, AB patients will receive low titer Group A convalescent plasma.
10. The Project Manager will place subsequent orders for convalescent plasma.
	1. Management will check the inventory on Mondays and email Project Manager.
	2. Project Manager will re-order and notify management.
	3. Staff should alert management if inventory falls to either 1 Group O or 1 Group A.

 **II. Ordering convalescent plasma**

1. The study team will determine in the ED if a patient should be enrolled in the study. They will also randomize the patients.
	1. The pharmacy will prepare the placebo when needed.
	2. Blood Bank will thaw the C3PO convalescent plasma when requested.
2. Study team will collect specimen and order a group/type.
3. The patient must have an ABORh performed within the last year per BB protocol.
	1. See *Plasma; BB.CP.1032*
4. Blood Bank will perform the Group/Type and determine if C3PO convalescent plasma is available that is ABO appropriate.
5. The study team will call to determine if inventory is available for the patient. (This MUST be from the C3PO convalescent plasma in Freezer 11.)
6. They will then place the order.

 **III. Processing the plasma order**

1. When ready to transfuse the physician/PI will order a **Prepare Convalescent Plasma** order and a **Transfuse** **Convalescent Plasma** order in Epic. This will print in the blood bank at the front desk where all add-on product orders print.
	1. These orders should arrive from the ED location with a comment **ED COVID Study**.
	2. A phone call should also be received from the study team to alert BB staff.
	3. This can only be ordered in Epic on patients who are 18 years or older AND have COVID-19 as a diagnosis. If the physician is having trouble ordering it may be one of these 2 criteria is not met.
2. The convalescent plasma will be retrieved from Freezer 11 and thawed per normal plasma procedure.
	1. See *Plasma; BB.CP.1032*
	2. Mark through the plasma removed on the packing list on the freezer.
3. The ED will be called to pick up the product.
4. The product will be issued in SCC per standard SOP.
5. The thawed plasma should be placed in a plastic bag for transport to the ED.
	1. Units should be transfused immediately so a cooler will not be needed.
6. Administration will occur via standard SOP.
7. Transfusion Reactions will be handled via standard SOP when reported to the Blood Bank.
8. Product lookbacks will be handled by the Blood Bank Management/Medical Director per standard SOP.
9. **Review/Revised/Implemented:**

 All protocols must be reviewed according to the Document Change Protocol.

 All new protocols that have major revisions must be signed by the CLIA Director.

 All reviewed protocols with minor revisions can be signed by the designated section Medical

 Director.

1. **Related Protocols:** Plasma; BB.CP.1032

1. **References**: NA

1. **Attachments**: NA
2. **Revised/Reviewed Dates and Signatures:**

Refer to archive history/Title21